

Remarks

Claims 1-7, 11-15, and new claims 19-20 are pending, with claims 8 and 16, and withdrawn claims 9, 10, 17, and 18, cancelled without prejudice or disclaimer.

The amendments in claims 1 and 2 are based on original claim 8, on page 8, lines 10-14, page 9, lines 7-9, page 10, lines 8-10 and 25-26 and page 11, lines 16-17 of the specification. New claims 19-20 are based on page 8, lines 29-31.

All rejections are moot by amendment.

In the instantly claimed process, foam with an overrun of 50 – 10,000 percent is formed first and then contacted with the mass of solid particles to disperse the surfactant and other foam components in the mass of solid particles and to agglomerate the particles to produce a granular material. Applicants' object is not stable foam, but rather a homogeneous dispersion of a liquid diluent, surfactant and optional other foam components in a mass of solid particles without the disadvantages experienced with dispersing a liquid in the mass of solid particles. In the process of the present invention a surprisingly homogeneous dispersion of the liquid diluent, surfactant and optional other foam components in the mass of solid particles is achieved without the need of expensive and complex atomizing devices that would be otherwise required for dispersing droplets of fine liquid in the mass of solid particles and without inhomogeneous distribution of liquid in the mass of solid particles (*page 1, lines 12-26 and page 10, lines 8-16 of the Applicants' specification*). This object is achieved by providing a foam of such quality that it has an overrun of 50 – 10,000 percent (*overrun (%) = [(volume foam – volume fluid)/volume fluid] x 1000, measured at 25°C and atmospheric pressure*).

In contrast, Davies et al. teach suspending a small quantity of a solid in a liquid (6.67% of solid Oxazepam) and only then addition of a gas. Davies et al. do not address anywhere how to effectively disperse a liquid and a surfactant in a mass of solid particles and

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how to effectively agglomerate the solid particles. Also, the instantly claimed process teaches that granular material is formed even before drying and the produced granular material is dried. In contrast, according to Davies' teaching a particulate (granular) material is only formed upon freeze-drying of liquid drops of suspensions. (*column 4, lines 18-20*).

As indicated by the Examiner, Parikh et al. do not teach coating of drug containing particles by application of a foam. Moreover, the instant claims further distinguish based upon the overrun of 50 to 10,000 percent limitation. Parikh et al. teach taste masked particles containing a core and a taste masking coating that optionally contains a surfactant (*paragraph 41*). The taste masking coating is applied to the core in the form of a solution (*paragraph 0043*). The taste masking coating can be overcoated with a texture masking coating layer, also in the form of a liquid solution (*paragraphs 0045 – 0050*, in particular *paragraph 50*, line 8 from the bottom). The coated particles can be processed to tablets by conventional direct compression, dry granulation or wet granulation techniques (*paragraph 56*), while Applicants point out that the wet granulation technique has the disadvantages discussed *on page 1, lines 12-26 of the Applicants' specification*.

McTeigue et al. do not teach a granulation process by application of a foam either, and in particular not with a foam with an overrun of 50 to 10,000 percent. McTeigue et al. disclose a process for applying a continuous polymeric coating over a core of particles. The coating solution comprises over 75 weight percent of acetone, based on the total weight of the coating solution (*column 6, lines 31-37*). In contrast, in the Applicants' process, the liquid diluent is not acetone and the amount of other additives in the Applicants' fluid composition (other than the surfactant i) and the liquid diluent ii)), if present, is only up to 25 weight percent, based upon the total weight of the fluid composition.

The Examiner has indicated in the past that the features upon which Applicants rely (i.e., the absence of acetone) are not recited in the claims. Applicants respectfully disagree.

The language in Claims 1 and 2 “*wherein the liquid diluent is a monofunctional alcohol, a paraffin oil, an animal oil, a vegetable oil or water*” clearly specifies the liquid diluent.

Moreover, Claims 1 and 2 clearly indicate that “the amount of other additives in the fluid composition, if present, is up to 25 weight percent, based upon the total weight of the fluid composition.” Accordingly, instantly claimed process clearly exclude the coating solution comprising over 75 weight percent of acetone as taught by McTeigue.

Lopez does not teach a granulation process by application of a foam either, and in particular not with a foam with an overrun of 50 to 10,000 percent. The compositions which are disclosed by Lopez, particularly in examples 1 to 3, comprise considerably more than 25 weight percent of additives (sugar, gelatin, acacia gum, talc, terra alba, calcium carbonate, C.M.C. and wheat flour) in addition to liquid diluents (water or alcohol) and surfactant (Pluronic F-68). Lopez et al. teach coating of solid particles with a high amount of sugar in a labor-intensive process. In Lopez’ examples 15 or even more coats are applied to the pharmaceutical solid form (*column 3, lines 51-53 and column 4, lines 10-11 and 37-38*).

To summarize, none of the cited references, neither alone or in combination, teaches a granulation process for producing a granular material using foam with an overrun of 50 to 10,000 percent, wherein the weight ratio between the foam and solid particles is from 1 : 20 to 1 : 0.2, to disperse the surfactant and other foam components in the mass of solid particles and to agglomerate the particles to produce a granular material, and drying the produced granular material.

Applicants will file a terminal disclaimer to overcome any nonstatutory obviousness-type double patenting if the rejection is repeated, once the claims are otherwise allowable.

The Examiner is cordially invited to call the undersigned if it will facilitate prosecution.

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